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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,059

05/08/2007

James Kowalski

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

YU, HONG

ART UNIT

PAPER NUMBER

4131

MAIL DATE

DELIVERY MODE

05/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,059	Applicant(s) KOWALSKI ET AL.	
	Examiner HONG YU	Art Unit 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,25-36,38-49 and 52-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23,25-36,38-49 and 52-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>g</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims/priority

Claims 1-23, 25-36, 38-49, and 52-55 are pending, claims 24, 37, 50, and 51 are canceled in this application. This application is a national stage entry of PCT/EP05/0040, filed on 01/17/2005.

Restriction

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-23, 25-33, 38-49, 52-55, drawn to compositions comprising DPP-IV.

Group II, claim(s) 34-36, drawn to process of making the composition comprising DPP_IV.

4. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), *the international application shall relate to one invention only or to a group of inventions.* Moreover, as stated in PCT Rule 13.2, the requirement of unity of invention referred to in PCT Rule 13.2 shall be fulfilled *where a group of inventions is claimed in one and the same international application only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.* The expression *special technical features* shall mean those technical features

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that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art, so linked, as to form a single general inventive concept.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the *special technical feature* in all groups is pharmaceutical composition comprising DPP-IV. The element cannot be a *special technical feature* under PCT Rule 13.2 because the element is shown in prior art. Balkan et al. (US 2003/0139434 A1) teach compositions in form of compressed tablet (example 1) comprising the same DPP-IV (LAF237) (paragraph 47) and excipients (example 1). Consequently, pharmaceutical composition comprising DPP-IV is not linked by the same or a corresponding special feature as to form a single general inventive concept.

Multiple inventors

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

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require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

7. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species election

8. Upon the selection of the invention mentioned above, a species election is necessary if the selected invention is motioned below.

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9. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

10. The species are as follows:

- a. various compositions with various percentages for each component in claims 1-12, 34-36, and 47-49;
- b. various weight of DPP-IV to weight of diluent ratios in claims 40 and 42;
- c. various particle sizes and distributions in claims 17, 18, 19, 22, and 23;
- d. various tablet thickness to tablet weight ratios in claims 16, 17, 18, and 21;
- e. various H₂O content in claims 18 and 20;
- f. various processes of preparing tablet in claims 34-36;
- g. various format of dosage unit in claims 29-33, 52, and 53.

11. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the special technical feature in all groups is a composition comprising (i) DPP-IV inhibitor; (ii) diluent; (iii) disintegrant; (iv) lubricant. The prior art Balkan et al. teach compositions in form of compressed tablet (example 1) comprising the same DPP-IV (LAF237) (paragraph 47) and excipients (example 1). These elements cannot be a special technical feature under PCT Rule 13.2 because the elements are shown in the prior art.

12. There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of

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search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

13. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The claims are deemed to correspond to the species listed above in the following manner:

- a. elect a single composition with a single percentage for each ingredient in claims 1-12, 34-36, and 47-49;
- b. elect a single weight of DPP-IV to weight of diluent ratio in claims 40 and 42;
- c. elect a single particle sizes and distributions in claims 17, 18, 19, 22, and 23;
- d. elect a single tablet thickness to tablet weight ratio in claims 16, 17, 18, and 21;
- e. elect a single H₂O content in claims 18 and 20;
- f. elect a single process in claims 34-36;
- g. elect a single format of dosage unit in claims 29-33, 52, and 53.

14. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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14. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

16. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

17. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Correspondence

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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is (571)270-1328.

The examiner can normally be reached on M-Th 8:20 am-6:50 pm.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HY

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4131